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PDUFA II LESSONS LEARNED AND FUTURE CHALLENGES

CBER'S PERSPECTIVE

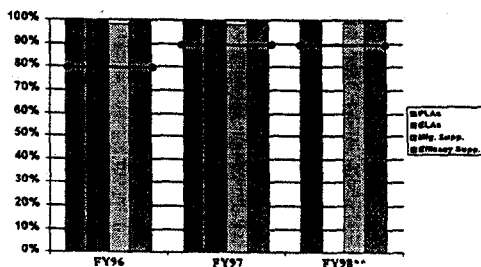


What's Working Well?

- CBER is meeting or exceeding PDUFA performance goals
- Center staff has a clear understanding of expectations regarding review of products
- Increased resources are available for meeting PDUFA goals.



CBER User Fee Review Performance
License Applications and Supplements
% of First Actions Within Goal*
By Cohort Fiscal Years 1996-1998



* PDUFA's Performance Goals: 75% for RPLAN, 100% for RPLAS, 75% for RPLSU.
** Represents FY98 RPLAS and RPLSU performance as reported in PDUFA's goals.
Data Source: CBER



00N-1364

183

CBER Review Performance FY 99 Cohort of User Fee Applications*						
Application Types	Numbers				Percent of Actions	
	Submitted	Filed	AP	RTF, UN, or WF	Within Goal	Overdue
New Products	8	6	1	2	80%	0%
Effectiveness Supplements	10	10	3	0	100%	0%
Manufacturing Supplements	394	394	221	0	99%	1%

AP=Approved, RTF=Return To File, UN=Unsubmittable For Filing, WF=Withdrawn Before Filing
 * Data as of 30 Aug 99 includes company entry changes and mergers

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What's Working Well? cont.

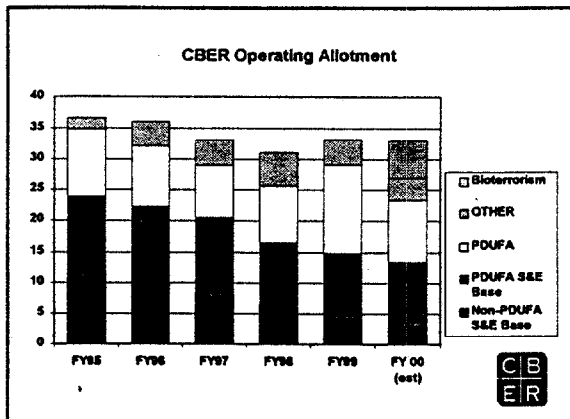
- Improvement of Information Technology and Data Management infrastructure.
- Improved quality of submissions
- Harmonization of regulatory requirements
- FDA's international leadership in review management and standards for review.



What's Not Working Well?

- There is a decrease in resources for non-PDUFA activities.
- The constraints placed on the use of PDUFA funds makes it difficult to achieve maximum efficiency in the Center.
- Decreased timelines stifle flexibility in the regulatory process.





- ### What's Not Working Well? cont.
- The proliferation of timeframes has created a "sweatshop" atmosphere resulting in increased staff turnover.
 - The PDUFA meeting management goals require a process that is more bureaucratic than should be necessary.
 - Loss of scientific research expertise
- CB
ER**

- ### Challenges for the Future
- Ensuring the quality of review under short timelines
 - Maintaining and enhancing the scientific expertise needed for review
 - Developing appropriate scientific infrastructure for the products of tomorrow
 - Adequate funding for non-PDUFA mission activities
- CB
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